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10/552,074	11/17/2005	Raymond Glocker	2590-134	8800

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EXAMINER	
DOUGHERTY, SEAN PATRICK	
ART UNIT	PAPER NUMBER
3736	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,074	GLOCKER ET AL.	
	Examiner	Art Unit	
	SEAN P. DOUGHERTY	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the *final* Office action based on the 10/552074 application filed November 17, 2005. Examiner acknowledges the amendments to claims 1-13 and new claims 14-20. Claims 1-20, as currently filed, are pending and have been considered below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by “applying simultaneously to it" in claim 1. For examination purposes, Examiner has interpreted "it" as the electrically conductive liquid substance.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7, 9-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knoll (US 6450972 B1) in view of Nicholas et al. (US 5433708 A).

Regarding claims 1 and 6, Knoll discloses a method for performing pressure measurements in a mammal by means of a pressure profile sensors technique, which comprising:

a) introducing into the mammal a catheter lumen having at least a portion of its wall which is sufficiently flexible to be deflected by external pressure ("pressure profile measurements, e.g. in urology, proctology, cardiology … carried out with the aid of catheters" Abstract lines 5-7; "tubular flexible hollow body" Abstract line 8 and col. 1, lines 30-38);

b) introducing progressively into the catheter lumen an electrically conductive liquid substance (col. 2 lines 13-14) while applying simultaneously to it alternative current ("alternating current" col. 2 line 1; "measurement of the electrical resistance, measurement of the electrical capacity, measurement of acoustic resonance" Abstract lines 14-16, Col. 4, lines 31-40);

c) detecting by means of an electrode (#21) placed at an external surface of the mammal a leakage current induced by the liquid substance traveling through the catheter ("electrical capacity is measured between the electrically conductive substance [I] and an electrically conductive medium [18] which surrounds the tube [1"]; "medium [18] can be a common salt solution, to which contact is provided with the aid of a metal electrode [21]" col. 5 lines 12-29);

d) transferring the leakage current thus recorded to a converter suitable to convert the leakage current provided thereto into corresponding pressure values ("the

pressure profile is here measured on the basis of a capacity measurement with the aid of a capacity measuring instrument #7" col. 5 lines 13-15); and

e) displaying the pressure values as such, or as a function of a measurement location or measurement period or both to afford corresponding pressure profiles (Figs. 1a-c and Col. 7, lines 3-16). Examiner notes that it is known to one of ordinary skill in that art that displaying results of a measurement is commonly known technique, the purpose of taking measurements is to display results in a multitude of forms for the use in medical diagnosis, surgery etc.

Knoll discloses an electrically conductive liquid substance (col. 2 lines 13-14). Knoll does not appear to explicitly disclose a method comprising applying mechanical oscillations to the electrically conductive liquid substance introduced progressively into the catheter lumen, progressing step-by-step. However, Nicholas et al. teaches a method comprising applying mechanical oscillations to an electrically conductive liquid substance introduced progressively into a catheter lumen, progressing step-by-step (#72; "inducing an oscillating flow of a … fluid" col. 1 lines 16-17; "power supply and controller may be connected to a mechanical actuator [72] which drives a syringe assembly [74] to create a reciprocating pump mechanism" col. 11 lines 38-41).

Knoll and Nicholas et al. are analogous art because they are from the same field of endeavor/problem solving area medical instruments, particularly catheters placed in a living mammal to perform a medical operation. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Knoll and Nicholas et al. before him or her to modify the electrically conductive liquid substance

introduced progressively into the catheter lumen of Knoll to be influenced by applying mechanical oscillations to the electrically conductive liquid substance, progressing the liquid step-by-step in the lumen of Nicholas et al.; this is applying a known technique of applying mechanical oscillation means to a known device ready for improvement, being an apparatus for performing pressure measurements, to yield the predictable result of the electroconductive liquid oscillating in movement when entering the lumen of the catheter. The motivation for doing so would have been "to realize a measurement system in which a pressure profile can be measured" as disclosed by Knoll (col. 1 lines 25-27) and to provide a "method for inducing an oscillating flow of … fluid" (col. 1 lines 16-17) as taught by Nicholas et al. Therefore, it would have been obvious to combine Knoll with Nicholas et al. to obtain the invention in the instant claims 1 and 6.

Regarding claim 13, Knoll discloses an apparatus for performing the method of claim 1, which comprises:

a source of an electrically conductive liquid substance (col. 2 lines 13-14) connected to an alternative current source ("alternating current" col. 2 line 1; "measurement of the electrical resistance, measurement of the electrical capacity, measurement of acoustic resonance" Abstract lines 14-16);

pumping (col. 4 line 35) means fitted directly to the source of liquid substance;

an electrode (#21) capable of being placed at the external surface of the mammal for recording and then transferring a detected leakage current to the converter ("electrical capacity is measured between the electrically conductive substance [I] and

an electrically conductive medium [18] which surrounds the tube [1"]; "medium [18] can be a common salt solution, to which contact is provided with the aid of a metal electrode [21]" col. 5 lines 12-29);

a converter ("the pressure profile is here measured on the basis of a capacity measurement with the aid of a capacity measuring instrument #7" col. 5 lines 13-15) suitable for deriving pressure values from the leakage current parameters which have been transferred thereto; and means suitable to display pressure values as such, or as a function of the measurement location or measurement period or both ("measurement system in which a pressure profile can be measured" col. 1 lines 26-27). Examiner notes that it is known to one of ordinary skill in that art that displaying results of a measurement is commonly known technique, the purpose of taking measurements is to display results in a multitude of forms for the use in medical diagnosis, surgery etc.

Knoll does not appear to explicitly disclose peristaltic pumping means and mechanical oscillation means connected downwards to peristaltic pumping means. However, Nicholas et al. teaches peristaltic pumping means and mechanical oscillation means connected downwards to peristaltic pumping means (#72; "inducing an oscillating flow of a … fluid" col. 1 lines 16-17; "power supply and controller may be connected to a mechanical actuator 72 which drives a syringe assembly 74 to create a reciprocating pump mechanism" col. 11 lines 38-41).

Knoll and Nicholas et al. are analogous art because they are from the same field of endeavor/problem solving area medical instruments, particularly catheters placed in a living mammal to perform a medical operation. At the time of the invention, it would

have been obvious to one of ordinary skill in the art, having the teachings of Knoll and Nicholas et al. before him or her to modify the fluid flow of Knoll to be influenced by the mechanical oscillation means connected downwards to peristaltic pumping means of Nicholas et al.; this is simply applying a known technique of applying mechanical oscillation means connected downwards to a peristaltic pump to a known device ready for improvement, being an apparatus for performing pressure measurements, to yield the predictable result of the electroconductive liquid oscillating in movement when entering the lumen of the catheter. The motivation for doing so would have been "to realize a measurement system in which a pressure profile can be measured" as disclosed by Knoll (col. 1 lines 25-27) and to provide a "method for inducing an oscillating flow of … fluid" (col. 1 lines 16-17) as taught by Nicholas et al. Therefore, it would have been obvious to combine Knoll with Nicholas et al. to obtain the invention in the instant claim 13.

Regarding claim 2, Knoll discloses a method wherein the alternative current is a low voltage and high frequency current ("alternating current" col. 2 line 1; "measurement of the electrical resistance, measurement of the electrical capacity, measurement of acoustic resonance" Abstract lines 14-16; "electrical voltages of U>10 mV" col. 2 line 2).

Knoll does not appear to explicitly disclose a method wherein the mechanical oscillations have controlled amplitude and frequency. However, Nicholas et al. discloses a method wherein the mechanical oscillations have controlled amplitude and frequency (col. 11 lines 51-54).

Knoll and Nicholas et al. are analogous art because they are from the same field of endeavor/problem solving area medical instruments, particularly catheters placed in a living mammal to perform a medical operation. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Knoll and Nicholas et al. before him or her to modify the alternative low voltage/high frequency current of Knoll to be influenced by applying mechanical oscillations wherein the mechanical oscillations have controlled amplitude and frequency of Nicholas et al.; this is applying a known technique of applying controlled mechanical oscillation means to a known device ready for improvement, being an apparatus for performing pressure measurements, to yield the predictable result of the electroconductive liquid oscillating in controlled movement when entering the lumen of the catheter. The motivation for doing so would have been "to realize a measurement system in which a pressure profile can be measured" as disclosed by Knoll (col. 1 lines 25-27) and to provide a "method for inducing an oscillating flow of … fluid" (col. 1 lines 16-17) as taught by Nicholas et al. Therefore, it would have been obvious to combine Knoll with Nicholas et al. to obtain the invention in the instant claim 2.

Regarding claims 3 and 15, Knoll discloses a method wherein the catheter is made of innocuous polymer plastic material (col. 2 line 5-7).

Regarding claim 4, Knoll discloses wherein the catheter is a single lumen (Fig. 8) or a multi-lumen catheter (Fig. 9).

Regarding claims 5 and 16, Knoll discloses a method wherein the electrically conductive liquid substance is an aqueous saline solution (col. 2 lines 13-14).

Regarding claims 7 and 17, Knoll discloses a method wherein the alternative current voltage applied to the electrically conductive liquid substance is between about 500mV/1V and about 6V/4V ("electrical voltages of U>10 mV" col. 2 line 2).

Regarding claims 9 and 14, Knoll does not appear to explicitly disclose a method wherein the mechanical oscillations applied to the electrically conductive liquid substance have a maximum amplitude of about 2/4mm and a maximum frequency of about 10/15 Hz. However, Nichols et al. teaches a method wherein the mechanical oscillations applied to the electrically conductive liquid substance have a maximum amplitude of about 2/4mm and a maximum frequency of about 10/15 Hz ("aspirating and expelling relatively small volumes of … medium through the catheter, typically in the range from about 0.1 ml to 3 ml" col. 3 lines 63-68; "catheters having diameters in the range from about 1.5 mm to 3 mm" col. 10 lines 32-34; "oscillation will typically be performed at from about 0.1 Hz to 5 Hz" col. 3 line 67-68).

Knoll and Nichols et al. are analogous art because they are from the same field of endeavor/problem solving area medical instruments, particularly catheters placed in a living mammal to perform a medical operation. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Knoll and

Nichols et al. before him or her to modify the fluid flow of Knoll to have the amplitude of about max. 2/4 mm and a frequency of about max 10/15 Hz of Nicholas et al.; this is simply applying a known technique of applying mechanical oscillation means connected downwards to a peristaltic pump to a known device ready for improvement being an apparatus for performing pressure measurements, to yield the predictable result of the electroconductive liquid oscillating in movement when entering the lumen of the catheter. The motivation for doing so would have been "to realize a measurement system in which a pressure profile can be measured" as disclosed by Knoll (col. 1 lines 25-27) and to provide a "method for inducing an oscillating flow of … fluid" (col. 1 lines 16-17) as taught by Nichols et al. Therefore, it would have been obvious to combine Knoll with Nichols et al. to obtain the invention in the instant claims 9 and 14.

Regarding claims 10, 11, 19 and 20, Knoll discloses performing real time pressure measurements in mammal body tracts or cavities or blood vessels using the method of claim 1("pressure profile measurements, e.g. in urology, proctology, cardiology … carried out with the aid of catheters" Abstract lines 5-7; "tubular flexible hollow body" Abstract line 8). Examiner notes that it known to one of ordinary skill in the art that urology and cardiology catheters correspond to pressure profiles measurements in the urinary tract/bladder and blood vessels, respectively. Examiner notes the phrase "such" renders the claim indefinite because it is unclear whether limitation following the phrase is part of the claimed invention.

Regarding claim 12, Knoll discloses performing ex-temporaneum pressure measurements using the method of claim 1 by recording the pressure values provided by the converter and by displaying them at a time different from that of the leakage current recording. Examiner notes that it is known to one of ordinary skill in that art that displaying results of a measurement is commonly known technique, the purpose of taking measurements is to display results in a multitude of forms for the use in medical diagnosis, surgery etc. by medical professionals.

Claim 8 and 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knoll (US 6450972 B1) as applied in claim 1 above, and further in view of Ogawa et al. (US 5846210 A).

Regarding claim 8 and 18, Knoll does not appear to explicitly disclose a method wherein the alternative current frequency applied to the electrically conductive liquid substance is comprised between about 60/80 and 130/120 kHz. However, Ogawa et al. teaches disclose a method wherein the alternative current frequency applied to the electrically conductive liquid substance is comprised between about 60/80 and 130/120 kHz ("high-frequency current is preferably such that the frequency and power are about 100" col. 8 lines 16-17).

Knoll and Ogawa et al. are analogous art because they are from the same field of endeavor/problem solving area medical instruments, particularly medical instruments placed in a living mammal to perform a medical operation. At the time of the invention, it

would have been obvious to one of ordinary skill in the art, having the teachings of Knoll and Ogawa et al. before him or her to modify the alternative current frequency applied to the electrically conductive liquid substance of Knoll to include the comprised current frequency to be between 60/80 and 130/120 kHz of Ogawa et al.; this is simply combining prior art elements of currents with specific ranges of the current frequencies to obtain predictable results of a current frequency in a desired range. It is known to one of ordinary skill in the art that alternative current frequencies can be applied to liquids in a multitude of ranges. Ogawa et al. teaches that current frequencies have already been applied in medical instruments. The motivation for doing so would have been "to realize a measurement system in which a pressure profile can be measured" as disclosed by Knoll (col. 1 lines 25-27) and to provide a provide a "high-frequency current through [a] guide wire" (Abstract lines 3-4) as taught by Ogawa et al. Therefore, it would have been obvious to combine Knoll with Nicholas et al. to obtain the invention in the instant claims 8 and 18.

Response to Arguments

Applicant's arguments filed April 30, 2008 have been fully considered but they are not persuasive.

Applicant argues on page 2 of the remarks that the rejection fails to present prima face case of obviousness because Knoll does not discloses a leakage current nor transferring a leakage current to a converter to convert the leakage current. The Examiner disagrees.

Knoll establishes in the abstract that the filling length to measure a pressure profile may be measured according to different methods, one of the methods including "measurement of electrical resistance".

Based on both inherency and laws of electrical resistance known to one of ordinary skill in the art, it would be obvious from the disclosure of Knoll that current is being measured. Ohms Law states, R=V/I, wherein (V) is the potential different across an object measured in volts, (I) is the current through the object measured in amperes and (R) is the resistance of the object, measured in ohms (see: http://en.wikipedia.org /wiki/Electrical_resistance). Knoll establishes the measurement of electrical resistance (R), the measurement (R) being taken with a current (I) at electrical voltages (V), thus current is being measured to determine the electrical resistance (R). Furthermore, measuring instrument [4] receives the resistance (and current) to convert the resistance (current).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Friday, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean P. Dougherty/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736